

**REMARKS**

Claims 1-18 are all the claims pending in the application; claims 1, 2, 4 and 6-18 have been withdrawn from consideration; claims 3 and 5 are objected to.

In view of the non-election of claims 1, 2, 4 and 6-18, these claims have been canceled from the application, without prejudice or disclaimer for the filing of these claims in a divisional application.

Claims 3 and 5 have been amended to more clearly recite the purpose for the steps included in the claims, i.e., a method for detecting a protease in a sample. Support for the amendment may be found in the specification, for example, at page 8, second paragraph.

No new matter has been added. Entry of the Amendment is respectfully requested.

**I. Information Disclosure Statement**

The Examiner has returned a signed and initialed copy of Form PTO 1449, listing the references submitted with the Information Disclosure Statement on July 31, 2001, in this application.

As the Examiner explains at pages 2-3 of the Office Action, the entries for the International Search Report and the European Search Report were drawn through because the Examiner was not able to find them in the parent application.

In response, Applicants include herewith a copy of both search reports to complete the Examiner's file. Each of the publications cited on the search reports was individually listed on the Form PTO 1449, filed July 31, 2001, and acknowledged by the Examiner.

## **II. Rejection of Claims Under 35 U.S.C. §112**

At page 4 of the Office Action, claims 3 and 5 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

The Examiner explains that while each claim is directed to a method for “measuring protease,” neither method claim recites any steps of actually measuring or quantifying a protease. The Examiner concludes that in the absence of such steps, it is unclear whether the claims are actually directed to the measurement of a protease, or merely to detection of a protease, and therefore the claims are indefinite.

In response, Applicants include herewith an amendment to the pending claims such that they now more clearly recite that the method is one for “detecting” a protease in a sample. Based on the steps recited in the rejected claims, it is clear that the method is designed to provide a qualitative result, i.e., use of the claimed method primary reveals whether or not a protease is present in a sample. Thus, the methods recited in the claims are properly characterized as “detecting” methods. In addition, support for the amendment may be found in the specification, for example, at page 8, second paragraph.

In view of these comments, and the amendment to the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

## **III. Double Patenting Rejection**

At page 5 of the Office Action, claims 3 and 5 are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,485,926, supported by Bayramoglu et al. (1992) (for pending claim 3) and Arai et al. (USP 4,786,595) (for pending claim 5).

As to claim 3, the Examiner contends that although the allegedly conflicting claims are not identical, they are not patentably distinct because claim 5 of the '926 patent is a species of a method, wherein pending claim 3 recites the generic method.

As to claim 5, the Examiner contends pending claim 5 recites a method of measuring a protease by contacting a sample with a thin membrane comprising a layer (a) comprising a substrate, protease inhibitor, and a hardener, and a layer (b) comprising a substrate and a hardener, wherein layer (b) is laminated to layer (a), detecting traces of digestion on the thin membrane, and comparing digestion on layer (a) with digestion on layer (b).

The Examiner states that while claim 5 of the '926 patent does not disclose laminating two layers on one support, Arai et al. teaches a multilayer analytical element for measuring protease wherein the element comprises a substrate. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to have laminated a layer with the components of layer (a) to a layer with the components of layer (b) in a multilayer analytical element, as taught by Arai et al., for use in the method of claim 5 of the '926 patent. The Examiner states that the motivation would have been to facilitate measurement of protease in a single sample using a single test element, as suggested by the methods of claims 1 and 2 of the '926 patent.

In response, while Applicants do not agree that the instantly claimed invention would be obvious over U.S. Patent No. 6,485,926, in view of Bayramoglu et al. and Arai et al., to further prosecution of the pending application, Applicants submit herewith a Terminal Disclaimer. As stated in the Terminal Disclaimer, Applicants disclaim the terminal part of any patent granted on the instant application which would extend beyond the expiration of the full statutory term of USP 6,485,926.

In view of the Terminal Disclaimer, the instant obviousness-type double patenting rejection is moot, and therefore Applicants respectfully request reconsideration and withdrawal of this rejection.

#### IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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